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TITLE: Effectiveness and Patient Acceptability of Stellate Ganglion Block (SGB) for Treatment of Posttraumatic Stress Disorder (PTSD) Symptoms among Active Duty Military Members

PRINCIPAL INVESTIGATOR: Bradford B. Walters, MD, PhD

CONTRACTING ORGANIZATION: Research Triangle Institute
Research Triangle Park, NC 27709-0155

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Bradford B. Walters, MD, PhD

email: bwalters@rti.org

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14. ABSTRACT

This study seeks to evaluate the effectiveness and acceptability of stellate ganglion block (SGB) for treatment of Posttraumatic Stress Disorder (PTSD) symptoms. We will conduct two parallel studies: a randomized, controlled trial (RCT) to evaluate the effectiveness of SGB for treating PTSD, and a qualitative study to determine the degree to which the procedure is deemed acceptable by active duty service members with PTSD, their spouses, and their providers. A total of 240 individuals will be enrolled for the RCT portion of the study; qualitative study participants will be convenience sampled from among the RCT participants. For the RCT study, participants will be randomized 2:1 active (SGB) to sham across three study sites. Participants will receive the study condition (active or sham) at weeks 0 (baseline) and 2, and assessments will be conducted at weeks 0, 2, 4, 6, and 8. For the qualitative study, individuals enrolled in the RCT will be asked to participate either in a focus group or an interview with their spouse. In addition, we will conduct focus groups and key informant interviews with providers: those who refer individuals to the study, and those who provide SGB to service members.

15. SUBJECT TERMS

Stellate ganglion block, Posttraumatic Stress Disorder, randomized controlled trial, qualitative research

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1. Introduction

This study seeks to evaluate the effectiveness and acceptability of stellate ganglion block (SGB) for treatment of Posttraumatic Stress Disorder (PTSD) symptoms. In order to do so, we will conduct two parallel studies: a randomized, controlled trial (RCT) to evaluate the effectiveness of SGB for treating PTSD, and a qualitative study to determine the degree to which the procedure is deemed acceptable by active duty service members with PTSD, their spouses, and their providers. A total of 240 individuals will be enrolled for the RCT portion of the study; qualitative study participants will be convenience sampled from among the RCT participants. For the RCT study, participants will be randomized 2:1 active (SGB) to sham across three study sites: Womack Army Medical Center (WAMC; Fort Bragg, NC), Tripler Army Medical Center (TAMC; Honolulu, HI), and Landstuhl Regional Medical Center (LRMC; Landstuhl, Germany). Participants will receive the study condition (active or sham) at weeks 0 (baseline) and 2, and assessments will be conducted at weeks 0, 2, 4, 6, and 8. For the qualitative study, individuals enrolled in the RCT who have received at least one SGB within the past 3 months will be asked to participate either in a focus group or an interview with their spouse. In addition, we will conduct focus groups and key informant interviews with providers: those who refer individuals to the study, and those who provide SGB to service members.

2. Keywords

Stellate ganglion block, Posttraumatic Stress Disorder, randomized controlled trial, qualitative research

3. Accomplishments

The major goals of this project for year one focused on regulatory and infrastructure activities. In sum, all clinical protocols and study instrumentation were completed, and Research Coordinators were hired and trained. IRB approval from WAMC was received, but HRPO (the U.S. Army Medical Research and Materiel Command's Human Research Protection Office) approval did not occur during year one. Although our approved Statement of Work estimated that the recruitment and enrollment of study participants would begin in month 10, these delays resulted in our not meeting this deadline.

During the course of year one, the initial study protocol and accompanying documents were submitted to the WAMC IRB, followed by four amendments over the course of 5 months (the last in December 2015). A fifth amendment was submitted in January 2016 based on feedback received from HRPO, and a final (sixth) amendment was submitted in March of 2016 (outside the scope of year one).

RCT- Task 1: Conduct Randomized Controlled Trial (Months 1-36)		
Subtask 1: Prepare Regulatory Documents and Research Protocols		
Milestone	**Complete?**	**Comments**
Finalize Clinical Protocol	Yes	
Receive Common Access Cards	No	Determined to be unnecessary
Receive all IRB and HRPO approvals	No	IRB approvals received however HRPO approval not received during year 1 (please see "Changes/Problems" for additional details)
Subtask 2: Develop Study Infrastructure		
Milestone	**Complete?**	**Comments**
Finalized Data Platforms	Yes	
Research Coordinators in place and trained	Yes	
Qualitative Study- Task 1: Conduct Qualitative Study		
Subtask 1: Prepare Regulatory Documents and Research Protocols		
Milestone	**Complete?**	**Comments**
Finalized qualitative study instrumentation	Yes	
Receive all IRB and HRPO approvals	No	WAMC IRB approval received, however HRPO approval not received during year 1 (please see "Changes/Problems" for additional details)

During year one, study staff were invited to give a presentation at the second annual Johns Hopkins Military and Veterans Health Institute conference entitled "Service Members and Veterans: PTSD Today and Tomorrow." Additionally, study staff submitted an abstract for presentation at the 2016 Special Operations Medical Association Scientific Assembly (SOMSA) and Exhibition, which was accepted. Also during year one, study staff traveled to each study site in order to meet with on-site staff, discuss site-specific logistics, and formulate a plan for moving forward.

During the upcoming project year, we anticipate receiving full HRPO approval (indeed it has been secured as of the time of this writing), beginning data collection for both the RCT and qualitative studies, traveling to each study site for regulatory compliance purposes, presenting at SOMSA and the Military Health System Research Symposium (MHSRS) 2016, and conducting quality assurance activities to ensure data integrity.

4. Impact

Nothing to report.

5. Changes/Problems

Changes: Nothing to report.

Problems: The approved Statement of Work included receipt of all IRB and regulatory clearance package approvals by the conclusion of month 9; however, the project team projection was overly aggressive. We received initial WAMC IRB (IRB of record) approval on 8 December 2015, which had been delayed by the discontinuation of IRBnet. As of the end of this reporting period, we had not yet received final HRPO approval. Because of these delays, site-specific materials could not be submitted to the WAMC IRB during year one of this grant, which will result in further delays in initiating data collection at LRMC and TAMC.

6. Products

During the course of year one, the study website was produced, populated, and refined: https://sgbstudy.rti.org/. Although an abstract for presentation at SOMSA was submitted and an invited presentation was requested for the Johns Hopkins conference, no presentations were given during this time period.

7. Participants and Other Collaborating Organizations

The following individuals have worked at least 160 hours on the project in total during project year one. There has been no change in support of the PIs or key personnel, and no other organizations were involved as partners.

Name	Project Role	Person months worked	Contributions to the project
Walters, Bradford	Principal Investigator	2	Management and substantive oversight (IRB/HRPO submissions, budget, substantive materials)
Rae Olmsted, Kristine	Co-Principal Investigator	7	Daily study operations; management and substantive oversight (IRB/HRPO submissions, budget, substantive materials)
Peeler, Russ	Logistics Task Manager	5	Coordination and oversight of all study logistics (hiring and training Research Coordinators, co-designing the control system, coordination with study sites)
Nelson, Jessica	Project Manager	1	Project management (budgeting, reporting, meeting coordination) support as well as assistance with development tasks as needed
Thomas, Emily	Computer Programming Team	2	Programming of web-based assessments
Zemonek, Richard	Computer Programming Task Leader	3	Oversight of all computer programming activities (web and assessment programming, co-designing the control system, quality control for all systems)

8. Special Reporting Requirements

Not applicable.

Appendix A:

Pre-Screener (Paper-and-Pencil Version)

Questions that require an answer have a red asterisk (*) at the end.

1. Have you ever received a stellate ganglion block?*
   - O No
   - O Yes

2. Are you currently on active duty?*
   - O No
   - O Yes

3. Do you expect to be stationed at your current duty location for at least 2 more months?*
   - O No
   - O Yes

4. Do you have personal access to the Internet and email?*
   - O No
   - O Yes

5. Are you currently in the process of medical board or medical retirement?*
   - O No
   - O Yes

6. Are you currently undergoing UCMJ or do you have any legal administrative actions being taken against you?*
   - O No
   - O Yes

Appendix B:

Screener (Paper-and-Pencil Version)

Thank you for volunteering to be a part of this important study that seeks to evaluate a potential new treatment for posttraumatic stress disorder. We would like to ask you some questions to determine whether this study is right for you. These questions should take you about 15 minutes to answer.

Questions that require an answer have a red asterisk (*) at the end.

*Demographics and Contact Information**

First name: _____

Last name: _____

Primary email: _____

Primary phone: _____

Secondary email: _____

Secondary phone: _____

Gender:

O Male O Female

Age: _____

Marital status:

- O Married
- O Living as married
- O Neither married nor living as married

Treatment facility:

- O Landstuhl Regional Medical Center
- O Tripler Army Medical Center
- O Womack Army Medical Center

Rank:

- O Junior Enlisted (E-1 to E-4)
- O Non-commissioned Officer (E-5 to E-6)
- O Senior Enlisted (E-7 to E-9)
- O Warrant Officer (W-1 to W-5)
- O Commissioned Officer (O-1 to O-9)

Which doctor or other provider referred you to this study?

- O Provider name: _____
- O Provider department (e.g., Family Medicine, Behavioral Health): _____

Have you completed a PTSD Checklist, or PCL, in the past year?
If yes, do you know your score?

- O No
- O Yes

If yes, do you know your score?

- O Enter score:_____
- O Don't Know

Are you SF-qualified, SEAL-qualified, or pararescue-qualified?

- O No
- O Yes

Last 4 digits of your Social Security Number: _____ (We use this information, along with your last name, to link your responses over time should it be determined that the study is right for you. This information will be kept secure at all times and will not be stored with any other information that you provide to us.)

Please provide the name of someone we can contact in the event that we need to reach you and are unable to locate you. We will only use this information in the event that we accidentally lose touch with you or in case of an emergency. This person should be someone you trust enough to share your medical information with, and who will know how to contact you. Examples might be a parent/guardian, spouse/significant other, or a very close friend.

*Emergency Contact Person**

First name: _____

Last name: _____

Phone number: _____

Alternate phone number: _____

Email address: _____

Alternate email address: _____

Relationship to participant: _____

Please provide the following information in case of an emergency.*

- O What is your CQ/duty phone number? _____
- O What is the name of your 1SG? _____
- O What is your 1SG's phone number? _____
- O What is the name of your CO? _____
- O What is your CO's phone number? _____

Study Eligibility

1. Have you had any changes in the medicines you take, or in their doses, in the **past 3 months**?*
   - O No
   - O Yes

   If yes, please list: _____

2. Has your medical provider discussed changing any of your medications in the **next 3 months**?*
   - O No
   - O Yes

   If yes, please explain: _____

3. Have you ever been offered or received treatment for posttraumatic stress from a Behavioral Health provider? This treatment could include medication, "talk therapy," or an exposure-based therapy in which you attempt to re-live painful events.*
   - O No [Go to Question 3A]
   - O Yes [Go to Question 4]

   3A. Would you like a referral to Behavioral Health? (Note that if you indicate yes, you will be ineligible for this study.)*
      - O No
      - O Yes

4. Have you previously had a stellate ganglion block (the procedure which this study is investigating)?*
   - O No
   - O Yes

5. Are you allergic to the anesthetic being used in this trial (ropivacaine) or to any other anesthetic drugs?*
   - O No
   - O Yes

6. [Females only] Are you planning on trying to become pregnant in the next 3 months?*
   - O No
   - O Yes

7. Have you used an anticoagulant medication in the past month? These are medications such as warfarin (Coumadin), dabigatran (Pradaxa), or rivaroxaban (Xarelto) that are commonly called blood thinners.*

- O No
- O Yes

8. Has a medical or mental health provider ever said that you were psychotic, or that you have schizophrenia or a schizoaffective disorder?*

- O No
- O Yes

8A. Has a doctor ever prescribed a medication called Lithium to you?*

- O No
- O Yes

8B. Has a medical or mental health provider ever said you were manic-depressive or had bipolar disorder?*

- O No
- O Yes

9. Have you received therapy for PTS/PTSD in the **past month**?*

- O No [Go to Question 10]
- O Yes [Go to Question 9A]

9A. Do you plan on continuing this treatment for the **next 3 months**? (Note that if you indicate yes, you will be ineligible for this study. You should discuss discontinuation of your current treatment with your care provider.)*

- O No
- O Yes

10. Have you ever been told you had a moderate or severe traumatic brain injury (TBI)?*

- O No
- O Yes

11. How often do you have a drink containing alcohol?*

- O Never
- O Monthly or less
- O 2 to 4 times a month
- O 2 to 3 times a week
- O 4 or more times a week

12. How many drinks containing alcohol do you have on a typical day when you are drinking?*

- O 1 or 2
- O 3 or 4
- O 5 or 6
- O 7, 8, or 9
- O 10 or more
- O Don't drink

13. How often do you have 6 or more drinks on one occasion?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

14. How often during the **past year** have you found that you were not able to stop drinking once you had started?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

15. How often during the **past year** have you failed to do what was normally expected from you because of drinking?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

16. How often during the **past year** have you needed a first drink in the morning to get yourself going after a heavy drinking session?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

17. How often during the **past year** have you had a feeling of guilt or remorse after drinking?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

18. How often during the **past year** have you been unable to remember what happened the night before because you had been drinking?*

- O Never
- O Less than monthly
- O Monthly
- O Weekly
- O Daily or almost daily

19. Have you or someone else been injured as a result of your drinking?*

- O No
- O Yes, but not in the past year
- O Yes, during the past year

20. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?*

- O No
- O Yes, but not in the past year
- O Yes, during the past year

21. Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, and mark the box to indicate how much you have been bothered by that problem *in the last month*.*

No.	Response	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past?					
2.	Repeated, disturbing *dreams* of a stressful experience from the past?					
3.	Suddenly *acting* or *feeling* as if a stressful experience *were happening* again (as if you were reliving it)?					
4.	Feeling *very upset* when *something reminded* you of a stressful experience from the past?					
5.	Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when *something reminded* you of a stressful experience from the past?					
6.	Avoid *thinking about* or *talking about* a stressful experience from the past or avoid *having feelings* related to it?					
7.	Avoid *activities* or *situations* because they *remind you* of a stressful experience from the past?					
8.	Trouble *remembering important parts* of a stressful experience from the past?					
9.	Loss of *interest in things that you used to enjoy?*					
10.	Feeling *distant* or *cut* off from other people?					
11.	Feeling *emotionally numb* or being unable to have loving feelings for those close to you?					
12.	Feeling as if your *future* will somehow be *cut short*?					
13.	Trouble *falling* or *staying asleep*?					
14.	Feeling *irritable* or having *angry outbursts*?					
15.	Having *difficulty concentrating*?					
16.	Being *"super alert"* or watchful on guard?					
17.	Feeling *jumpy* or easily startled?					

22. Listed below are a number of difficult or stressful things that sometimes happen to people. For each event check one or more of the boxes to the right to indicate that: (a) it **happened to you** personally; (b) you **witnessed it** happen to someone else; (c) you **learned about it** happening to a close family member or close friend; (d) you were exposed to it as **part of your job** (for example, paramedic, police, military, or other first responder); (e) you're **not sure** if it fits; or (f) it **doesn't apply** to you.*

Be sure to consider your **entire life** (growing up as well as adulthood) as you go through the list of events.

	Happened to Me	Witnessed It	Learned About It	Part Of My Job	Not Sure	Doesn't Apply
1. Natural disaster (for example, flood, hurricane, tornado, earthquake)						
2. Fire or explosion						
3. Transportation accident (for example, car accident, boat accident, train wreck, plane crash)						
4. Serious accident at work, home, or during recreational activity						
5. Exposure to toxic substance (for example, dangerous chemicals, radiation)						
6. Physical assault (for example, being attacked, hit, slapped, kicked, beaten up)						
7. Assault with a weapon (for example, being shot, stabbed, threatened with a knife, gun, bomb)						
8. Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)						
9. Other unwanted or uncomfortable sexual experience						
10. Combat or exposure to a war-zone (in the military or as a civilian)						
11. Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war)						
12. Life-threatening illness or injury						
13. Severe human suffering						
14. Sudden violent death (for example, homicide, suicide)						
15. Sudden accidental death						
16. Serious injury, harm, or death you caused to someone else						
17. Any other very stressful event or experience						

23. In the **past 2 months**, did you…*

	Yes	No
a. Want to harm yourself or to hurt or to injure yourself?		
b. Think about suicide?		
c. Have a suicide plan?		
d. Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die?		
e. Deliberately injure yourself without intending to kill yourself?		
f. Attempt suicide?		
g. Did you ever make a suicide attempt?		

23A. Do you **currently**…*

	Yes	No
a. Want to harm yourself or to hurt or to injure yourself?		
b. Think about suicide?		
c. Have a suicide plan?		
d. Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expect or intend to die?		

Appendix C:

Baseline Assessment (Paper-and-Pencil Version)

Thank you for your willingness to participate in this important study. The questions that follow should take you about 20 minutes to answer.

Also, you may notice that some of the questions look very similar. We are aware of this and assure you that all questions are necessary. Please answer all questions honestly as best you can.

Questions that require an answer have a red asterisk (*) at the end.

1. Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then mark your answer to the right to indicate how much you have been bothered by that problem in the past two weeks.*

   In the past 2 weeks, how much were you bothered by:

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?					
2. Repeated, disturbing dreams of the stressful experience?					
3. Suddenly feeling or acting as if the stressful experience were actually happening again *(as if you were actually back there reliving it)*?					
4. Feeling very upset when something reminded you of the stressful experience?					
5. Having strong physical reactions when something reminded you of the stressful experience *(for example, heart pounding, trouble breathing, sweating)*?					
6. Avoiding memories, thoughts, or feelings related to the stressful experience?					
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?					
8. Trouble remembering important parts of the stressful experience?					
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?					
10. Blaming yourself or someone else for the stressful experience or what happened after it?					
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?					
12. Loss of interest in activities that you used to enjoy?					
13. Feeling distant or cut off from other people?					
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?					

In the past 2 weeks, how much were you bothered by:

	Not at all	A little bit	Moderately	Quite a bit	Extremely
15. Irritable behavior, angry outbursts, or acting aggressively?					
16. Taking too many risks or doing things that could cause you harm?					
17. Being "superalert" or watchful or on guard?					
18. Feeling jumpy or easily startled?					
19. Having difficulty concentrating?					
20. Trouble falling or staying asleep?					

2. Do you currently have a diagnosis of posttraumatic stress (PTS) or posttraumatic stress disorder (PTSD) from a medical or behavioral health provider?*

   O Yes [Go to Question 2A]

   O No [Go to Question 3]

   2A. If yes, when did you receive this diagnosis?*

   Month:_____ Year:_____

   2B. If no, approximately when did you first begin to experience the symptoms of PTS/PTSD?*

   Month:_____ Year:_____

3. Have you smoked at least 100 cigarettes in your entire life? (That would be 5 or more packs in your entire life.)

   O Yes [Go to Question 4]

   O No [Go to Question 8]

4. How old were you when you first started smoking cigarettes regularly? (Smoking regularly means smoking at least one cigarette a day for 30 days or longer.)

   O I have never smoked at least one cigarette a day for 30 days or longer [Go to Question 8]

   O ___ (age in years) [Go to Question 5]

5. When was the last time you smoked regularly? (Smoking regularly means smoking at least one cigarette a day for 30 days or longer.)
   - O I smoke regularly now [Go to Question 6]
   - O I smoked regularly in the past year but not in the past month [Go to Question 7]
   - O ___ years ago [Go to Question 7]
   - O I never smoked cigarettes regularly [Go to Question 8]

6. In the **past 30 days**, how many cigarettes did you **usually** smoke on a typical day?
   - O More than 35 cigarettes (about 2 packs or more a day) [Go to Question 8]
   - O 26–35 cigarettes (about 1 ½ packs a day) [Go to Question 8]
   - O 16–25 cigarettes (about 1 pack a day) [Go to Question 8]
   - O 6–15 cigarettes (about ½ pack a day) [Go to Question 8]
   - O 2–5 cigarettes a day [Go to Question 8]
   - O Less than 1 cigarette a day on average [Go to Question 8]
   - O I did not smoke any cigarettes in the past 30 days [Go to Question 8]
   - O I never smoked cigarettes [Go to Question 8]

7. At the time you last smoked regularly, how many cigarettes did you **usually** smoke on a typical day?
   - O More than 35 cigarettes (about 2 packs or more a day)
   - O 26–35 cigarettes (about 1 ½ packs a day)
   - O 16–25 cigarettes (about 1 pack a day)
   - O 6–15 cigarettes (about ½ pack a day)
   - O 2–5 cigarettes a day
   - O Less than 1 cigarette a day, on average
   - O I did not smoke any cigarettes in the past 30 days
   - O I never smoked cigarettes

8. Have you ever been a regular user of chewing tobacco, snuff, or other smokeless tobacco? (Regular use means using chewing tobacco, snuff, or other smokeless tobacco **at least once a day** for **30 days or longer**.)
   - O Yes [Go to Question 9]
   - O No [Go to Question 17]

9. How old were you when you first started using chewing tobacco, snuff, or other smokeless tobacco regularly? (Regular use means **at least once a day** for **30 days or longer**.)
   - O I have never used chewing tobacco, snuff, or other smokeless tobacco once a day for 30 days or longer [Go to Question 17]
   - O ___ (age in years) [Go to Question 10]

10. When was the last time you used chewing tobacco, snuff, or other smokeless tobacco regularly? (Regular use means **at least once a day** for **30 days or longer**.)
    - O I use chewing tobacco, snuff, or other smokeless tobacco regularly now [Go to Question 11]
    - O I used chewing tobacco regularly in the past year but not in the past month [Go to Question 14]
    - O ___ years ago [Go to Question14]
    - O I have never used chewing tobacco, snuff, or other smokeless tobacco [Go to Question 17]

11. Think about the **past 30 days**. How often on the average have you used chewing tobacco, snuff, or other smokeless tobacco?
    - O About every day [Go to Question 12]
    - O 5–6 days a week [Go to Question 12]
    - O 3–4 days a week [Go to Question 12]
    - O 1–2 days a week [Go to Question 12]
    - O 2–3 days a month [Go to Question 12]
    - O About once a month [Go to Question 12]
    - O Less than once a month [Go to Question 12]
    - O I never used chewing tobacco, snuff, or other smokeless tobacco [Skip to Question 17]

12. How many times do you **usually** use smokeless tobacco on a typical day?
    - O More than 10 times [Go to Question 13]
    - O 8–9 times [Go to Question 13]
    - O 6–7 times [Go to Question 13]
    - O 4–5 times [Go to Question 13]
    - O 2–3 times [Go to Question 13]
    - O 1 or fewer times [Go to Question 13]
    - O I never use chewing tobacco, snuff, or other smokeless tobacco regularly [Go to Question 17]

13. Approximately how long do you dip or chew each time you used?
    - O More than 2 hours [Go to Question 17]
    - O 90 minutes to 2 hours [Go to Question 17]
    - O 1 hour to 89 minutes [Go to Question 17]
    - O 45 minutes to 59 minutes [Go to Question 17]
    - O 30 minutes to 44 minutes [Go to Question 17]
    - O 15 minutes to 29 minutes [Go to Question 17]
    - O Less than 15 minutes [Go to Question 17]
    - O I never use chewing tobacco, snuff, or other smokeless tobacco regularly [Go to Question 17]

14. At the time you last used chewing tobacco, snuff, or other smokeless tobacco regularly, how often on the average did you use chewing tobacco, snuff, or other smokeless tobacco?
    - O About every day [Go to Question 15]
    - O 5–6 days a week [Go to Question 15]
    - O 3–4 days a week [Go to Question 15]
    - O 1–2 days a week [Go to Question 15]
    - O 2–3 days a month [Go to Question 15]
    - O About once a month [Continue to Question 15]
    - O Less than once a month [Go to Q15]
    - O I never used chewing tobacco, snuff, or other smokeless tobacco [Go to Question 17]

15. At the time you last used chewing tobacco, snuff, or other smokeless tobacco regularly, how many times did you **usually** use on a typical day?
    - O More than 10 times [Go to Question 16]
    - O 8–9 times [Go to Question 16]
    - O 6–7 times [Go to Question 16]
    - O 4–5 times [Go to Question 16]
    - O 2–3 times [Go to Question 16]
    - O 1 or fewer times [Go to Question 16]
    - O I never use chewing tobacco, snuff, or other smokeless tobacco regularly [Go to Question 17]

16. At the time you last used chewing tobacco, snuff, or other smokeless tobacco regularly, approximately how long did you dip or chew each time you used?

- O More than 2 hours [Go to Question 17]
- O 90 minutes to 2 hours [Go to Question 17]
- O 1 hour to 89 minutes [Go to Question 17]
- O 45 minutes to 59 minutes [Go to Question 17]
- O 30 minutes to 44 minutes [Go to Question 17]
- O 15 minutes to 29 minutes [Go to Question 17]
- O Less than 15 minutes [Go to Question 17]
- O I never use chewing tobacco, snuff, or other smokeless tobacco regularly [Go to Question 17]

17. Over the past 2 weeks, how often have you been bothered by any of the following problems?

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c Trouble falling or staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
g. Trouble concentrating on things, such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
i. Thoughts that you would be better off dead or of hurting yourself in some way				

17A. If you checked off **any** problems in Question 2, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people?

- O Not difficult at all
- O Somewhat difficult
- O Very difficult
- O Extremely difficult

18. Over the **past 2 weeks**, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
a. Feeling nervous, anxious or on edge				
b. Not being able to stop or control worrying				
c. Worrying too much about different things				
d. Trouble relaxing				
e. Being so restless that it is hard to sit still				
f. Becoming easily annoyed or irritable				
g. Feeling afraid as if something awful might happen				

19. The following questions ask about how you have been feeling during the **past 30 days**. For each question, please mark the answer that best describes how often you had this feeling.

During the **past 30 days**, about how often did you feel…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Nervous?					
b. Hopeless?					
c. Restless or fidgety?					
d. So depressed that nothing could cheer you up?					
e. That everything was an effort?					
f. Worthless?					

20. In general, would you say your health is:
    - O Excellent
    - O Very good
    - O Good
    - O Fair
    - O Poor

During a typical day, does **your health now limit you** in the following activities? If so, how much?

21. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
    - O Yes, limited a lot
    - O Yes, limited a little
    - O No, not limited at all

22. Climbing SEVERAL flights of stairs:
    - O Yes, limited a lot
    - O Yes, limited a little
    - O No, not limited at all

During the **past month**, have you had any of the following problems with your work or other regular activities **as a result of your physical health**?

23. ACCOMPLISHED LESS than you would like:
    - O Yes
    - O No

24. Were limited in the KIND of work or other activities:
    - O Yes
    - O No

During the **past month**, were you limited in the kind of work you do or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

25. ACCOMPLISHED LESS than you would like:
    - O Yes
    - O No

26. Didn't do work or other activities as CAREFULLY as usual:
    - O Yes
    - O No

27. During the **PAST MONTH**, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
    - O Not at all
    - O A little bit
    - O Moderately
    - O Quite a bit
    - O Extremely

The next three questions are about how you feel and how things have been **during the past month**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past month**…

28. Have you felt calm and peaceful?
    - O All of the time
    - O Most of the time
    - O A good bit of the time
    - O Some of the time
    - O A little of the time
    - O None of the time

29. Did you have a lot of energy?
    - O All of the time
    - O Most of the time
    - O A good bit of the time
    - O Some of the time
    - O A little of the time
    - O None of the time

30. Have you felt downhearted and blue?
    - O All of the time
    - O Most of the time
    - O A good bit of the time
    - O Some of the time
    - O A little of the time
    - O None of the time

31. **During the past month**, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?
    - O All of the time
    - O Most of the time
    - O A good bit of the time
    - O Some of the time
    - O A Little of the time
    - O None of the time

32. Using the scale below, please rate your pain in the past 2 weeks:

No pain					**Moderate pain**					**Worst possible pain**
0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**

33. How often do you have a drink containing alcohol?
    - O Never
    - O Monthly or less
    - O Two to four times a month
    - O Two to three times a week
    - O Four or more times a week

34. How many drinks containing alcohol do you have on a typical day when you are drinking?
    - O 1 or 2
    - O 3 or 4
    - O 5 or 6
    - O 7, 8, or 9
    - O 10 or more
    - O Do not drink

35. How often do you have 6 or more drinks on one occasion?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

36. How often during the **past year** have you found that you were not able to stop drinking once you had started?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

37. How often during the **past year** have you failed to do what was normally expected from you because of drinking?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

38. How often during the **past year** have you needed a first drink in the morning to get yourself going after a heavy drinking session?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

39. How often during the **past year** have you had a feeling of guilt or remorse after drinking?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

40. How often during the **past year** have you been unable to remember what happened the night before because you had been drinking?
    - O Never
    - O Less than monthly
    - O Monthly
    - O Weekly
    - O Daily or almost daily

41. Have you or someone else been injured as a result of your drinking?
    - O No
    - O Yes, but not in the past year
    - O Yes, during the past year

42. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down?
    - O No
    - O Yes, but not in the past year
    - O Yes, during the past year

43. Please enter all medications you are currently taking in the spaces below. You can enter the brand name or the generic name. Please also fill out appropriate information regarding dosage and frequency.

Medication name (Generic or brand name)	**What does the label on the bottle or package say is the amount of medication contained in one dose of this medication?**	**Is this mg, g, or other?**	**How many doses do you or did you take of this medication each day? (If the number of doses you took each day changed over the past 6 months, please tell us the most recent number of doses you took each day.)**	**In the past 3 months, during how many months did you take this medication? (0 to 3)**	**Are you taking this medication now? (Yes or No)**	**On how many of the past 30 days did you take this medication? (0 to 30)**

44. Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, and mark the box to indicate how much you have been bothered by that problem in the **past 2 weeks**.*

No.	Response	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past?					
2.	Repeated, disturbing *dreams* of a stressful experience from the past?					
3.	Suddenly *acting* or *feeling* as if a stressful experience *were happening* again (as if you were reliving it)?					
4.	Feeling *very upset* when *something reminded* you of a stressful experience from the past?					
5.	Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when *something reminded* you of a stressful experience from the past?					
6.	Avoid *thinking about* or *talking about* a stressful experience from the past or avoid *having feelings* related to it?					
7.	Avoid *activities* or *situations* because they *remind you* of a stressful experience from the past?					
8.	Trouble *remembering important parts* of a stressful experience from the past?					
9.	Loss of interest in things that you used to enjoy?					
10.	Feeling *distant* or *cut* off from other people?					
11.	Feeling *emotionally numb* or being unable to have loving feelings for those close to you?					
12.	Feeling as if your *future* will somehow be *cut short*?					
13.	Trouble falling or staying asleep?					
14.	Feeling irritable or having angry outbursts?					
15.	Having difficulty concentrating?					
16.	Being *"super alert"* or watchful on guard?					
17.	Feeling *jumpy* or easily startled?					

The next set of questions asks about thoughts you may have had of hurting yourself or others in the **past 2 months**.

45. In the **past 2 months**, did you…*

	Yes	No
a. Want to harm yourself or to hurt or to injure yourself?		
b. Think about suicide?		
c. Have a suicide plan?		
d. Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die?		
e. Deliberately injure yourself without intending to kill yourself?		
f. Attempt suicide?		
g. Did you ever make a suicide attempt?		

45A. Do you currently…*

	Yes	No
a. Want to harm yourself or to hurt or to injure yourself?		
b. Think about suicide?		
c. Have a suicide plan?		
d. Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die?		

Appendix D:

2-Week Follow-Up Assessment (Paper-and-Pencil Version)

Thank you for your willingness to participate in this important study. The questions that follow should take you about 8 minutes to answer.

Also, you may notice that some of the questions look very similar. We are aware of this and assure you that all questions are necessary. Please answer all questions honestly as best you can.

Questions that require an answer have a red asterisk (*) at the end.

1. Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then mark your answers to the right to indicate how much you have been bothered by that problem in the past 2 weeks.*

   In the past 2 weeks, how much were you bothered by…

	Not at all	A little bit	Moderately	Quite a bit	Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?					
2. Repeated, disturbing dreams of the stressful experience?					
3. Suddenly feeling or acting as if the stressful experience were actually happening again *(as if you were actually back there reliving it)*?					
4. Feeling very upset when something reminded you of the stressful experience?					
5. Having strong physical reactions when something reminded you of the stressful experience *(for example, heart pounding, trouble breathing, sweating)*?					
6. Avoiding memories, thoughts, or feelings related to the stressful experience?					
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?					
8. Trouble remembering important parts of the stressful experience?					
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?					
10. Blaming yourself or someone else for the stressful experience or what happened after it?					
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?					
12. Loss of interest in activities that you used to enjoy?					

	Not at all	A little bit	Moderately	Quite a bit	Extremely
13. Feeling distant or cut off from other people?					
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?					
15. Irritable behavior, angry outbursts, or acting aggressively?					
16. Taking too many risks or doing things that could cause you harm?					
17. Being “superalert” or watchful or on guard?					
18. Feeling jumpy or easily startled?					
19. Having difficulty concentrating?					
20. Trouble falling or staying asleep?					

2. Overall, how would you compare the way you’re feeling now to how you felt before having the study procedure?*

- O Much better than before
- O Somewhat better than before
- O Neither better nor worse
- O Somewhat worse than before
- O Much worse than before

3. The following questions ask about how you have been feeling during the **past 30 days**. For each question, please mark the answer that best describes how often you had this feeling.

During the **past 30 days**, about how often did you feel…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Nervous?					
b. Hopeless?					
c. Restless or fidgety?					
d. So depressed that nothing could cheer you up?					
e. That everything was an effort?					
f. Worthless?					

4. Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully and mark your answer to indicate how much you have been bothered by that problem in the **past 2 weeks**.*

No.	Response	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Repeated, disturbing memories, thoughts, or images of a stressful experience from the past?					
2.	Repeated, disturbing dreams of a stressful experience from the past?					
3.	Suddenly acting or feeling as if a stressful experience were happening again (as if you were reliving it)?					
4.	Feeling very upset when something reminded you of a stressful experience from the past?					
5.	Having physical reactions (e.g., heart pounding, trouble breathing, or sweating) when something reminded you of a stressful experience from the past?					
6.	Avoid thinking about or talking about a stressful experience from the past or avoid having feelings related to it?					
7.	Avoid activities or situations because they remind you of a stressful experience from the past?					
8.	Trouble remembering important parts of a stressful experience from the past?					
9.	Loss of interest in things that you used to enjoy?					
10.	Feeling distant or cut off from other people?					
11.	Feeling emotionally numb or being unable to have loving feelings for those close to you?					
12.	Feeling as if your future will somehow be cut short?					
13.	Trouble falling or staying asleep?					
14.	Feeling irritable or having angry outbursts?					
15.	Having difficulty concentrating?					
16.	Being “super alert” or watchful on guard?					
17.	Feeling jumpy or easily startled?					

5. In the **past 2 months**, did you…*

		Yes	No
a.	Want to harm yourself or to hurt or to injure yourself?		
b.	Think about suicide?		
c.	Have a suicide plan?		
d.	Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die?		
e.	Deliberately injure yourself without intending to kill yourself?		
f.	Attempt suicide?		
g.	Did you ever make a suicide attempt?		

5A. Do you currently…*

		Yes	No
a.	Want to harm yourself or to hurt or to injure yourself?		
b.	Think about suicide?		
c.	Have a suicide plan?		
d.	Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expect or intend to die?		

Appendix E:

4-Week Follow-Up Assessment (Web Version)

Thank you for your willingness to participate in this important study. The questions that follow should take you about 20 minutes to answer. Depending on how you respond, some questions may be skipped. It may seem like the questions are out of order- please know that this is normal. Depending on the answers you provide, you may not be asked all of the possible questions. We do this to save you time.

Also, you may notice that some of the questions look very similar. We are aware of this and assure you that all questions are necessary. Please answer all questions honestly as best you can.

Questions that require an answer have a red asterisk (*) at the end.

If you are completing this assessment on a smart phone, please turn the screen to landscape.

1. Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then mark your answer to the right to indicate how much you have been bothered by that problem in the **past two weeks**.*

   In the **past two weeks**, how much were you bothered by:

	Not at all	*A little bit*	*Moderately*	*Quite a bit*	*Extremely*
1. Repeated, disturbing, and unwanted memories of the stressful experience? (PCL5_1)	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience? (PCL5_2)	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again *(as if you were actually back there reliving it)*? (PCL5_3)	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience? (PCL5_4)	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience *(for example, heart pounding, trouble breathing, sweating)*? (PCL5_5)	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience? (PCL5_6)	0	1	2	3	4
7. Avoiding external reminders of the stressful experience *(for example, people, places, conversations, activities, objects, or situations)*? (PCL5_7)	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience? (PCL5_8)	0	1	2	3	4

9. Having strong negative beliefs about yourself, other people, or the world *(for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)*? (PCL5_9)	**0**	**1**	**2**	**3**	**4**
10. Blaming yourself or someone else for the stressful experience or what happened after it? (PCL5_10)	**0**	**1**	**2**	**3**	**4**
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame? (PCL5_11)	**0**	**1**	**2**	**3**	**4**
12. Loss of interest in activities that you used to enjoy?	**0**	**1**	**2**	**3**	**4**
13. Feeling distant or cut off from other people?	**0**	**1**	**2**	**3**	**4**
14. Trouble experiencing positive feelings *(for example, being unable to feel happiness or have loving feelings for people close to you)*? (PCL5_14)	**0**	**1**	**2**	**3**	**4**
15. Irritable behavior, angry outbursts, or acting aggressively? (PCL5_15)	**0**	**1**	**2**	**3**	**4**
16. Taking too many risks or doing things that could cause you harm? (PCL5_16)	**0**	**1**	**2**	**3**	**4**
17. Being "superalert" or watchful or on guard?	**0**	**1**	**2**	**3**	**4**
18. Feeling jumpy or easily startled? (PCL5_18)	**0**	**1**	**2**	**3**	**4**
19. Having difficulty concentrating? (PCL5_19)	**0**	**1**	**2**	**3**	**4**
20. Trouble falling or staying asleep? (PCL5_20)	**0**	**1**	**2**	**3**	**4**

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2. Overall, how would you compare the way you're feeling now to how you felt before having the study procedure? * (HOWFEELING)
   - Much better than before (5)
   - Somewhat better than before (4)
   - Neither better nor worse (3)
   - Somewhat worse than before (2)
   - Much worse than before (1)

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3. Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

	Not at all (0)	**Several days (1)**	**More than half the days (2)**	**Nearly every day (3)**
a. Little interest or pleasure in doing things (PHQ9_a)	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless (PHQ9_b)	☐	☐	☐	☐
c Trouble falling or staying asleep, or sleeping too much (PHQ9_c)	☐	☐	☐	☐
d. Feeling tired or having little energy (PHQ9_d)	☐	☐	☐	☐
e. Poor appetite or overeating (PHQ9_e)	☐	☐	☐	☐
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down (PHQ9_f)	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television (PHQ9_g)	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual (PHQ9_h)	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way (PHQ9_i)	☐	☐	☐	☐

3a. If you checked off *any* problems in question 3, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people? (PHQ9_diff)

☐ Not difficult at all (0)
☐ Somewhat difficult (1)
☐ Very difficult (2)
☐ Extremely difficult (3)

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4. Over the **last 2 weeks**, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
a. Feeling nervous, anxious or on edge (GAD7_a)	0	1	2	3
b. Not being able to stop or control worrying (GAD7_b)	0	1	2	3
c. Worrying too much about different things (GAD7_c)	0	1	2	3
d. Trouble relaxing (GAD7_d)	0	1	2	3
e. Being so restless that it is hard to sit still (GAD7_e)	0	1	2	3

f. Becoming easily annoyed or irritable (GAD7_f)	0	1	2	3
g. Feeling afraid as if something awful might happen (GAD7_g)	0	1	2	3

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5. The following questions ask about how you have been feeling during the **past 30 days**. For each question, please mark the answer that best describes how often you had this feeling.

During the **past 30 days**, about how often did you feel…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Nervous? (K6_a)	1	2	3	4	5
b. Hopeless? (K6_b)	1	2	3	4	5
c. Restless or fidgety? (K6_c)	1	2	3	4	5
d. So depressed that nothing could cheer you up? (K6_d)	1	2	3	4	5
e. That everything was an effort? (K6_e)	1	2	3	4	5
f. Worthless? (K6_f)	1	2	3	4	5

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6. In general, would you say your health is: (SF12_1)
   - ☐ Excellent (1)
   - ☐ Very Good (2)
   - ☐ Good (3)
   - ☐ Fair (4)
   - ☐ Poor (5)

During a typical day, does **your health now limit you** in the following activities? If so, how much?

7. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf: (SF12_2)
   - ☐ Yes, Limited a Lot (1)
   - ☐ Yes, Limited a Little (2)
   - ☐ No, Not Limited at All (3)
8. Climbing SEVERAL flights of stairs: (SF12_3)
   - ☐ Yes, Limited a Lot (1)
   - ☐ Yes, Limited a Little (2)
   - ☐ No, Not Limited at All (3)

During the **past month**, have you had any of the following problems with your work or other regular activities **as a result of your physical health?**

9. ACCOMPLISHED LESS than you would like: (SF12_4)
   - ☐ Yes (1)
   - ☐ No (0)
10. Were limited in the KIND of work or other activities: (SF12_5)
   - ☐ Yes (1)
   - ☐ No (0)

During the **past month**, were you limited in the kind of work you do or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

11. ACCOMPLISHED LESS than you would like: (SF12_6)
   - ☐ Yes (1)
   - ☐ No (0)
12. Didn't do work or other activities as CAREFULLY as usual: (SF12_7)
   - ☐ Yes (1)
   - ☐ No (0)
13. During the **PAST MONTH**, how much did PAIN interfere with your normal work (including both work outside the home and housework)? (SF12_8)
   - ☐ Not At All (1)
   - ☐ A Little Bit (2)
   - ☐ Moderately (3)
   - ☐ Quite A Bit (4)
   - ☐ Extremely (5)

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The next three questions are about how you feel and how things have been during the **past month**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past month**…

14. Have you felt calm and peaceful? (SF12_9)
   - ☐ All of the Time (0)
   - ☐ Most of the Time (1)
   - ☐ A Good Bit of the Time (2)
   - ☐ Some of the Time (3)
   - ☐ A Little of the Time (4)
   - ☐ None of the Time (5)
15. Did you have a lot of energy? (SF12_10)
   - ☐ All of the Time (0)
   - ☐ Most of the Time (1)
   - ☐ A Good Bit of the Time (2)
   - ☐ Some of the Time (3)
   - ☐ A Little of the Time (4)
   - ☐ None of the Time (5)

16. Have you felt downhearted and blue? (SF12_11)

- ☐ All of the Time (0)
- ☐ Most of the Time (1)
- ☐ A Good Bit of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

17. **During the past month**, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)? (SF12_12)

- ☐ All of the Time (0)
- ☐ Most of the Time (1)
- ☐ A Good Bit of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

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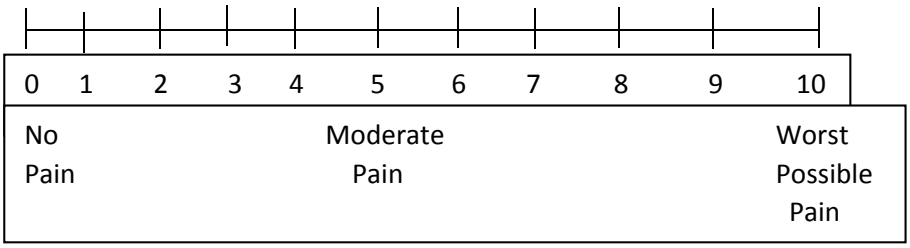
18. Using the scale below, please rate your pain in the **past 2 weeks**: (PAIN)



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19. How often do you have a drink containing alcohol? (AUDIT_1)

Never (0)
Monthly or less (1)
Two to four times a month (2)
Two to three times a week (3)
Four or more times a week (4)

20. How many drinks containing alcohol do you have on a typical day when you are drinking? (AUDIT_2)

1 or 2 (0)
3 or 4 (1)
5 or 6 (2)
7, 8, or 9 (3)
10 or more (4)
Don't Drink (-1)

21. How often do you have six or more drinks on one occasion? (AUDIT_3)

Never (0)
Less than monthly (1)

Monthly (2)
Weekly (3)
Daily or almost daily (4)

22. How often during the **last year** have you found that you were not able to stop drinking once you had started? (AUDIT_4)

Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

23. How often during the **last year** have you failed to do what was normally expected from you because of drinking? (AUDIT_5)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

24. How often during the **last year** have you needed a first drink in the morning to get yourself going after a heavy drinking session? (AUDIT_6)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

25. How often during the **last year** have you had a feeling of guilt or remorse after drinking? (AUDIT_7)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

26. How often during the **last year** have you been unable to remember what happened the night before because you had been drinking? (AUDIT_8)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

27. Have you or someone else been injured as a result of your drinking? (AUDIT_9)
No (0)
Yes, but not in the last year (1)
Yes, during the last year (2)

28. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down? (AUDIT_10)
No (0)
Yes, but not in the last year (2)
Yes, during the last year (4)

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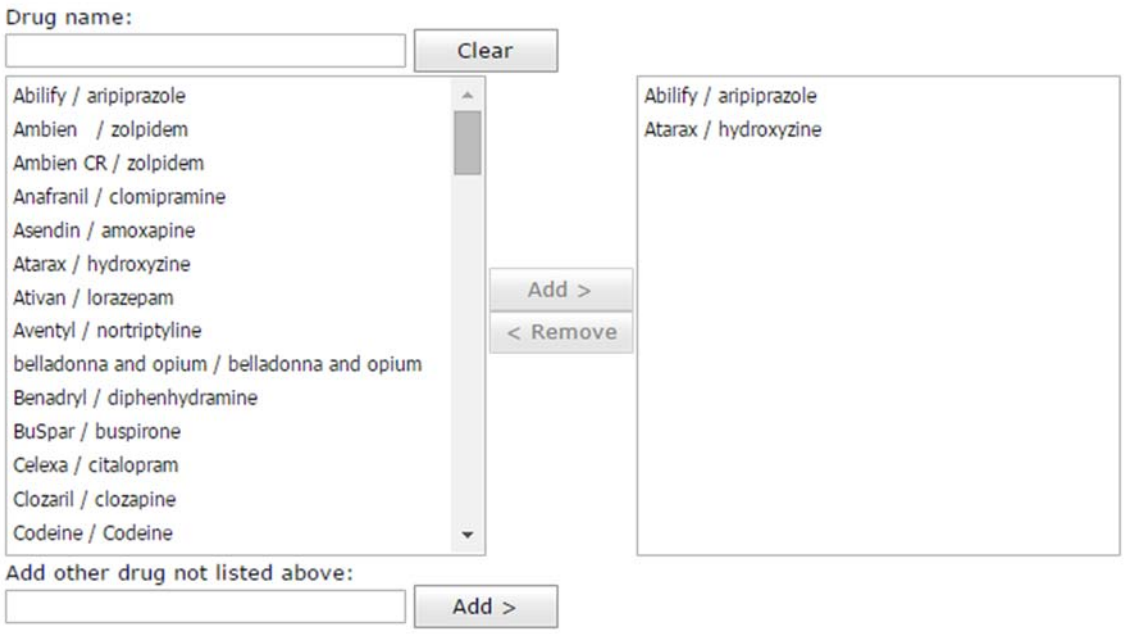
29. Please begin entering the name of any medication you are currently taking in the box on the left. You can enter the brand name or the generic name. When you see the medication you are looking for, highlight it and click the "Add >" button to move the medication name to the box on the right. (MedsList)



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You indicated that you take [FILL] medications. Please answer the following questions for [FIRST MEDICATION INDICATED].

29a. What does the label on the bottle or package say is the amount of medication contained in one dose of this medication? Make sure to include the decimal point if there is one.

DOSAGE _____ **(MedsDose_1)**

29b. Is this: **(MedsUnits_1)**

___ mg (0)

___ g (1)

___ other (2)

29c. How many doses do you or did you take of this medication each day? (If the number of doses you took each day changed over the past **6 months**, please tell us the most recent number of doses you took each day.)

DOSES _____ **(MedsNumDose_1)**

29d. In the past **3 months**, during how many months did you take this medication?

MONTHS _____ **(MedsMonths_1)**

29e. Are you taking this medication now? **(MedsNow_1)**

___ Yes **(1)**

___ No **(0)**

29f. If yes, on how many of the past **30 days** did you take this medication?

DAYS _____ **(Meds30d _1)**

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30. Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully, and mark the box to indicate how much you have been bothered by that problem in the **last 2 weeks.***

No.	Response	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
1.	Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past? (PCLC_1)					
2.	Repeated, disturbing *dreams* of a stressful experience from the past? (PCLC_2)					
3.	Suddenly *acting* or *feeling* as if a stressful experience *were happening* again (as if you were reliving it)? (PCLC_3)					
4.	Feeling *very upset* when *something reminded* you of a stressful experience from the past? (PCLC_4)					
5.	Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when *something reminded* you of a stressful experience from the past? (PCLC_5)					
6.	Avoid *thinking about* or *talking about* a stressful experience from the past or avoid *having feelings* related to it? (PCLC_6)					
7.	Avoid *activities* or *situations* because they *remind you* of a stressful experience from the past? (PCLC_7)					
8.	Trouble *remembering important parts* of a stressful experience from the past? (PCLC_8)					
9.	Loss of *interest in things that you used to enjoy?* (PCLC_9)					
10.	Feeling *distant* or *cut* off from other people? (PCLC_10)					
11.	Feeling *emotionally numb* or being unable to have loving feelings for those close to you? (PCLC_11)					
12.	Feeling as if your *future* will somehow be *cut short*? (PCLC_12)					
13.	Trouble *falling* or *staying asleep*? (PCLC_13)					

14.	Feeling *irritable* or having *angry outbursts*? (PCLC_14)					
15.	Having *difficulty concentrating*? (PCLC_15)					
16.	Being *"super alert"* or watchful on guard? (PCLC_16)					
17.	Feeling *jumpy* or easily startled? (PCLC_17)					

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31. When you began your participation in this study, you were informed that you would be receiving either a true stellate ganglion block (an active procedure) or an imitation procedure (frequently called a placebo). At this point in the study, do you believe you received an active procedure or an imitation procedure?* (PROCGUESS)

Active_____ **(1)**

Imitation_____ **(0)**

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The next set of questions asks about thoughts you may have had of hurting yourself or others in the **past 2 months**.

32. In the **past 2 months**, did you…*

	Yes (1)	**No (0)**
a. Want to harm yourself or to hurt or to injure yourself? (SI_a)	☐	☐
b. Think about suicide? (SI_b)	☐	☐
c. Have a suicide plan? (SI_c)	☐	☐
d. Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? (SI_d)	☐	☐
e. Deliberately injure yourself without intending to kill yourself? (SI_e)	☐	☐
f. Attempt suicide? (SI_f)	☐	☐
g. Did you ever make a suicide attempt? (SI_g)	☐	☐

[IF PARTICIPANT SCORES POSITIVE ON ITEMS 32 ABOVE, ADMINISTER Q32b_sub BELOW.]

32b_sub. Do you **currently**…*

	Yes (1)	**No (0)**
a. Want to harm yourself or to hurt or to injure yourself? (SI_sub_a)	☐	☐
b. Think about suicide? (SI_sub_b)	☐	☐
c. Have a suicide plan? (SI_sub_c)	☐	☐
d. Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? (SI_sub_d)	☐	☐

Appendix F:

6-Week Follow-Up Assessment (Web Version)

Thank you for your willingness to participate in this important study. The questions that follow should take you about 8 minutes to answer. Depending on how you respond, some questions may be skipped. It may seem like the questions are out of order- please know that this is normal. Depending on the answers you provide, you may not be asked all of the possible questions. We do this to save you time.

Also, you may notice that some of the questions look very similar. We are aware of this and assure you that all questions are necessary. Please answer all questions honestly as best you can.

Questions that require an answer have a red asterisk (*) at the end.

If you are completing this assessment on a mobile device, please turn the screen to landscape.

4. Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then mark your answers to the right to indicate how much you have been bothered by that problem in the **past two weeks**. *

In the **past two weeks**, how much were you bothered by:

	Not at all	*A little bit*	*Moderately*	*Quite a bit*	*Extremely*
1. Repeated, disturbing, and unwanted memories of the stressful experience? (PCL5_1)	0	1	2	3	4
2. Repeated, disturbing dreams of the stressful experience? (PCL5_2)	0	1	2	3	4
3. Suddenly feeling or acting as if the stressful experience were actually happening again *(as if you were actually back there reliving it)*? (PCL5_3)	0	1	2	3	4
4. Feeling very upset when something reminded you of the stressful experience? (PCL5_4)	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience *(for example, heart pounding, trouble breathing, sweating)*? (PCL5_5)	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience? (PCL5_6)	0	1	2	3	4
7. Avoiding external reminders of the stressful experience *(for example, people, places, conversations, activities, objects, or situations)*? (PCL5_7)	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience? (PCL5_8)	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world *(for example, having*	0	1	2	3	4

***thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)*? (PCL5_9)**					
10. Blaming yourself or someone else for the stressful experience or what happened after it? (PCL5_10)	**0**	**1**	**2**	**3**	**4**
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame? (PCL5_11)	**0**	**1**	**2**	**3**	**4**
12. Loss of interest in activities that you used to enjoy? (PCL5_12)	**0**	**1**	**2**	**3**	**4**
13. Feeling distant or cut off from other people? (PCL5_13)	**0**	**1**	**2**	**3**	**4**
14. Trouble experiencing positive feelings *(for example, being unable to feel happiness or have loving feelings for people close to you)*? (PCL5_14)	**0**	**1**	**2**	**3**	**4**
15. Irritable behavior, angry outbursts, or acting aggressively? (PCL5_15)	**0**	**1**	**2**	**3**	**4**
16. Taking too many risks or doing things that could cause you harm? (PCL5_16)	**0**	**1**	**2**	**3**	**4**
17. Being "superalert" or watchful or on guard? (PCL5_17)	**0**	**1**	**2**	**3**	**4**
18. Feeling jumpy or easily startled? (PCL5_18)	**0**	**1**	**2**	**3**	**4**
19. Having difficulty concentrating? (PCL5_19)	**0**	**1**	**2**	**3**	**4**
20. Trouble falling or staying asleep? (PCL5_20)	**0**	**1**	**2**	**3**	**4**

5. Overall, how would you compare the way you're feeling now to how you felt before having the study procedure? * (HOWFEELING)
   - Much better than before (5)
   - Somewhat better than before (4)
   - Neither better nor worse (3)
   - Somewhat worse than before (2)
   - Much worse than before (1)

3. The following questions ask about how you have been feeling during the **past 30 days**. For each question, please mark the answer that best describes how often you had this feeling.

During the **past 30 days**, about how often did you feel…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
g. Nervous? (K6_a)	1	2	3	4	5
h. Hopeless? (K6_b)	1	2	3	4	5
i. Restless or fidgety? (K6_c)	1	2	3	4	5
j. So depressed that nothing could cheer you up? (K6_d)	1	2	3	4	5
k. That everything was an effort? (K6_e)	1	2	3	4	5
l. Worthless? (K6_f)	1	2	3	4	5

4. Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Please read each one carefully and mark your answer to indicate how much you have been bothered by that problem in the **last 2 weeks**.*

No.	Response	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
1.	Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past? (PCLC_1)					
2.	Repeated, disturbing *dreams* of a stressful experience from the past? (PCLC_2)					
3.	Suddenly *acting* or *feeling* as if a stressful experience *were happening* again (as if you were reliving it)? (PCLC_3)					
4.	Feeling *very upset* when *something reminded* you of a stressful experience from the past? (PCLC_4)					
5.	Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when *something reminded* you of a stressful experience from the past? (PCLC_5)					
6.	Avoid *thinking about* or *talking about* a stressful experience from the past or avoid *having feelings* related to it? (PCLC_6)					
7.	Avoid *activities* or *situations* because they *remind you* of a stressful experience from the past? (PCLC_7)					
8.	Trouble *remembering important parts* of a stressful experience from the past? (PCLC_8)					
9.	Loss of *interest in things that you used to enjoy?* (PCLC_9)					
10.	Feeling *distant* or *cut* off from other people? (PCLC_10)					
11.	Feeling *emotionally numb* or being unable to have loving feelings for those close to you? (PCLC_11)					
12.	Feeling as if your *future* will somehow be *cut short*? (PCLC_12)					
13.	Trouble *falling* or *staying asleep*? (PCLC_13)					

14.	Feeling *irritable* or having *angry outbursts*? (PCLC_14)					
15.	Having *difficulty concentrating*? (PCLC_15)					
16.	Being *"super alert"* or watchful on guard? (PCLC_16)					
17.	Feeling *jumpy* or easily startled? (PCLC_17)					

5. In the **past 2 months**, did you… *

	Yes (1)	**No (0)**
a. Want to harm yourself or to hurt or to injure yourself? (SI_a)	☐	☐
b. Think about suicide? (SI_b)	☐	☐
c. Have a suicide plan? (SI_c)	☐	☐
d. Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? (SI_d)	☐	☐
e. Deliberately injure yourself without intending to kill yourself? (SI_e)	☐	☐
f. Attempt suicide? (SI_f)	☐	☐
g. Did you ever make a suicide attempt? (SI_g)	☐	☐

[IF PARTICIPANT SCORES POSITIVE ON ITEM 5 ABOVE, ADMINISTER Q5b_sub BELOW.]

5b_sub. Do you **currently**…*

Yes (1) No (0)

a. Want to harm yourself or to hurt or to injure yourself? (SI_sub_a)

b. Think about suicide? (SI_sub_b)

c. Have a suicide plan? (SI_sub_c)

d. Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expect or intend to die? (SI_sub_d)

Appendix G:

8-Week Follow-Up Assessment (Web Version)

Thank you for your willingness to participate in this important study. The questions that follow should take you about 20 minutes to answer. Depending on how you respond, some questions may be skipped. It may seem like the questions are out of order- please know that this is normal. Depending on the answers you provide, you may not be asked all of the possible questions. We do this to save you time.

Also, you may notice that some of the questions look very similar. We are aware of this and assure you that all questions are necessary. Please answer all questions honestly as best you can.

Questions that require an answer have a red asterisk (*) at the end.

If you are completing this assessment on a smart phone, please turn the screen to landscape.

1. Listed below are a number of difficult or stressful things that sometimes happen to people. For each event check one or more of the boxes to the right to indicate that: (a) it **happened to you** personally; (b) you **witnessed it** happen to someone else; (c) you **learned about it** happening to a close family member or close friend; (d) you were exposed to it as **part of your job** (for example, paramedic, police, military, or other first responder); (e) you're **not sure** if it fits; or (f) it **doesn't apply** to you.*

Be sure to consider your **entire life** (growing up as well as adulthood) as you go through the list of events.

	Happened to me (5)	Witnessed it (4)	Learned about it (3)	Part of my job (2)	Not Sure (1)	Doesn't Apply (0)
1. Natural disaster (for example, flood, hurricane, tornado, earthquake) (LEC_1)						
2. Fire or explosion (LEC_2)						
3. Transportation accident (for example, car accident, boat accident, train wreck, plane crash) (LEC_3)						
4. Serious accident at work, home, or during recreational activity (LEC_4)						
5. Exposure to toxic substance (for example, dangerous chemicals, radiation) (LEC_5)						
6. Physical assault (for example, being attacked, hit, slapped, kicked, beaten up) (LEC_6)						
7. Assault with a weapon (for example, being shot, stabbed,						

threatened with a knife, gun, bomb) (LEC_7)						
8. Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm) (LEC_8)						
9. Other unwanted or uncomfortable sexual experience (LEC_9)						
10. Combat or exposure to a war-zone (in the military or as a civilian) (LEC_10)						
11. Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war) (LEC_11)						
12. Life-threatening illness or injury (LEC_12)						
13. Severe human suffering (LEC_13)						
14. Sudden violent death (for example, homicide, suicide) (LEC_14)						
15. Sudden accidental death (LEC_15)						
16. Serious injury, harm, or death you caused to someone else (LEC_16)						
17. Any other very stressful event or experience (LEC_17)						

2. Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then mark your answer to the right to indicate how much you have been bothered by that problem in the **past two weeks**.*

In the **past two weeks**, how much were you bothered by:

	Not at all	***little bit***	***Moderately***	***Quite a bit***	***Extremely***
1. Repeated, disturbing, and unwanted memories of the stressful experience? (PCL5_1)	**0**	**1**	**2**	**3**	**4**
2. Repeated, disturbing dreams of the stressful experience? (PCL5_2)	**0**	**1**	**2**	**3**	**4**
3. Suddenly feeling or acting as if the stressful experience were actually happening again *(as if you were actually back there reliving it)*? (PCL5_3)	**0**	**1**	**2**	**3**	**4**

4. Feeling very upset when something reminded you of the stressful experience? (PCL5_4)	0	1	2	3	4
5. Having strong physical reactions when something reminded you of the stressful experience *(for example, heart pounding, trouble breathing, sweating)*? (PCL5_5)	0	1	2	3	4
6. Avoiding memories, thoughts, or feelings related to the stressful experience? (PCL5_6)	0	1	2	3	4
7. Avoiding external reminders of the stressful experience *(for example, people, places, conversations, activities, objects, or situations)*? (PCL5_7)	0	1	2	3	4
8. Trouble remembering important parts of the stressful experience? (PCL5_8)	0	1	2	3	4
9. Having strong negative beliefs about yourself, other people, or the world *(for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)*? (PCL5_9)	0	1	2	3	4
10. Blaming yourself or someone else for the stressful experience or what happened after it? (PCL5_10)	0	1	2	3	4
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame? (PCL5_11)	0	1	2	3	4
12. Loss of interest in activities that you used to enjoy? (PCL5_12)	0	1	2	3	4
13. Feeling distant or cut off from other people? (PCL5_13)	0	1	2	3	4
14. Trouble experiencing positive feelings *(for example, being unable to feel happiness or have loving feelings for people close to you)*? (PCL5_14)	0	1	2	3	4
15. Irritable behavior, angry outbursts, or acting aggressively? (PCL5_15)	0	1	2	3	4
16. Taking too many risks or doing things that could cause you harm? (PCL5_16)	0	1	2	3	4
17. Being “superalert” or watchful or on guard? (PCL5_17)	0	1	2	3	4
18. Feeling jumpy or easily startled? (PCL5_18)	0	1	2	3	4

19. Having difficulty concentrating? (PCL5_19)	**0**	**1**	**2**	**3**	**4**
20. Trouble falling or staying asleep? (PCL5_20)	**0**	**1**	**2**	**3**	**4**

3. Overall, how would you compare the way you're feeling now to how you felt before having the study procedure? * (HOWFEELING)
   - Much better than before (5)
   - Somewhat better than before (4)
   - Neither better nor worse (3)
   - Somewhat worse than before (2)
   - Much worse than before (1)

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4. Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

	Not at all (0)	**Several days (1)**	**More than half the days (2)**	**Nearly every day (3)**
a. Little interest or pleasure in doing things (PHQ9_a)	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless (PHQ9_b)	☐	☐	☐	☐
c Trouble falling or staying asleep, or sleeping too much (PHQ9_c)	☐	☐	☐	☐
d. Feeling tired or having little energy (PHQ9_d)	☐	☐	☐	☐
e. Poor appetite or overeating (PHQ9_e)	☐	☐	☐	☐
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down (PHQ9_f)	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television (PHQ9_g)	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual (PHQ9_h)	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way (PHQ9_i)	☐	☐	☐	☐

4a. If you checked off *any* problems in question 4, how **difficult** have these problems made it for you to do your work, take care of things at home, or get along with other people? (PHQ9_diff)

☐ Not difficult at all (0)
☐ Somewhat difficult (1)
☐ Very difficult (2)
☐ Extremely difficult (3)

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5. Over the **last 2 weeks**, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
h. Feeling nervous, anxious or on edge (GAD7_a)	0	1	2	3
i. Not being able to stop or control worrying (GAD7_b)	0	1	2	3

j. Worrying too much about different things (GAD7_c)	0	1	2	3
k. Trouble relaxing (GAD7_d)	0	1	2	3
l. Being so restless that it is hard to sit still (GAD7_e)	0	1	2	3
m. Becoming easily annoyed or irritable (GAD7_f)	0	1	2	3
n. Feeling afraid as if something awful might happen (GAD7_g)	0	1	2	3

INSERT PAGE BREAK HERE

6. The following questions ask about how you have been feeling during the **past 30 days**. For each question, please mark the answer that best describes how often you had this feeling.

During the **past 30 days**, about how often did you feel…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
m. Nervous? (K6_a)	1	2	3	4	5
n. Hopeless? (K6_b)	1	2	3	4	5
o. Restless or fidgety? (K6_c)	1	2	3	4	5
p. So depressed that nothing could cheer you up? (K6_d)	1	2	3	4	5
q. That everything was an effort? (K6_e)	1	2	3	4	5
r. Worthless? (K6_f)	1	2	3	4	5

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7. In general, would you say your health is: (SF12_1)
   - ☐ Excellent (1)
   - ☐ Very Good (2)
   - ☐ Good (3)
   - ☐ Fair (4)
   - ☐ Poor (5)

During a typical day, does **your health now limit you** in the following activities? If so, how much?

8. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf: (SF12_2)
   - ☐ Yes, Limited a Lot (1)
   - ☐ Yes, Limited a Little (2)

- ☐ No, Not Limited at All (3)

9. Climbing SEVERAL flights of stairs: (SF12_3)
   - ☐ Yes, Limited a Lot (1)
   - ☐ Yes, Limited a Little (2)
   - ☐ No, Not Limited at All (3)

During the **past month**, have you had any of the following problems with your work or other regular activities **as a result of your physical health?**

10. ACCOMPLISHED LESS than you would like: (SF12_4)
    - ☐ Yes (1)
    - ☐ No (0)
11. Were limited in the KIND of work or other activities: (SF12_5)
    - ☐ Yes (1)
    - ☐ No (0)

During the **past month**, were you limited in the kind of work you do or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

12. ACCOMPLISHED LESS than you would like: (SF12_6)
    - ☐ Yes (1)
    - ☐ No (0)
13. Didn't do work or other activities as CAREFULLY as usual: (SF12_7)
    - ☐ Yes (1)
    - ☐ No (0)
14. During the **PAST MONTH**, how much did PAIN interfere with your normal work (including both work outside the home and housework)? (SF12_8)
    - ☐ Not At All (1)
    - ☐ A Little Bit (2)
    - ☐ Moderately (3)
    - ☐ Quite A Bit (4)
    - ☐ Extremely (5)

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The next three questions are about how you feel and how things have been **during the past month**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past month**…

15. Have you felt calm and peaceful? (SF12_9)
    - ☐ All of the Time (0)
    - ☐ Most of the Time (1)
    - ☐ A Good Bit of the Time (2)
    - ☐ Some of the Time (3)
    - ☐ A Little of the Time (4)
    - ☐ None of the Time (5)
16. Did you have a lot of energy? (SF12_10)
    - ☐ All of the Time (0)
    - ☐ Most of the Time (1)
    - ☐ A Good Bit of the Time (2)

- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

17. Have you felt downhearted and blue? (SF12_11)
- ☐ All of the Time (0)
- ☐ Most of the Time (1)
- ☐ A Good Bit of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

18. **During the past month**, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)? (SF12_12)
- ☐ All of the Time (0)
- ☐ Most of the Time (1)
- ☐ A Good Bit of the Time (2)
- ☐ Some of the Time (3)
- ☐ A Little of the Time (4)
- ☐ None of the Time (5)

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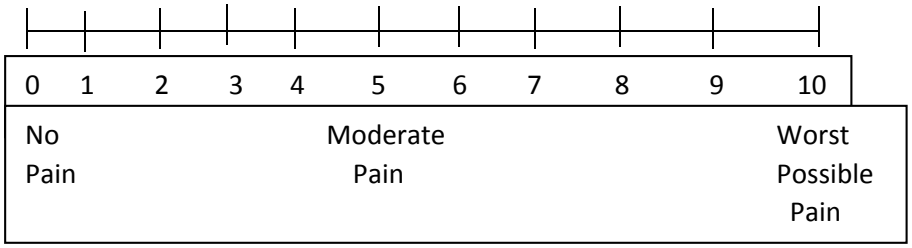
19. Using the scale below, please rate your pain in the **past 2 weeks**: (PAIN)



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20. How often do you have a drink containing alcohol? (AUDIT_1)

Never (0)
Monthly or less (1)
Two to four times a month (2)
Two to three times a week (3)
Four or more times a week (4)

21. How many drinks containing alcohol do you have on a typical day when you are drinking? (AUDIT_2)

1 or 2 (0)
3 or 4 (1)
5 or 6 (2)
7, 8, or 9 (3)
10 or more (4)
Don't Drink (-1)

22. How often do you have six or more drinks on one occasion? (AUDIT_3)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

23. How often during the **last year** have you found that you were not able to stop drinking once you had started? (AUDIT_4)

Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

24. How often during the **last year** have you failed to do what was normally expected from you because of drinking? (AUDIT_5)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

25. How often during the **last year** have you needed a first drink in the morning to get yourself going after a heavy drinking session? (AUDIT_6)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

26. How often during the **last year** have you had a feeling of guilt or remorse after drinking? (AUDIT_7)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

27. How often during the **last year** have you been unable to remember what happened the night before because you had been drinking? (AUDIT_8)
Never (0)
Less than monthly (1)
Monthly (2)
Weekly (3)
Daily or almost daily (4)

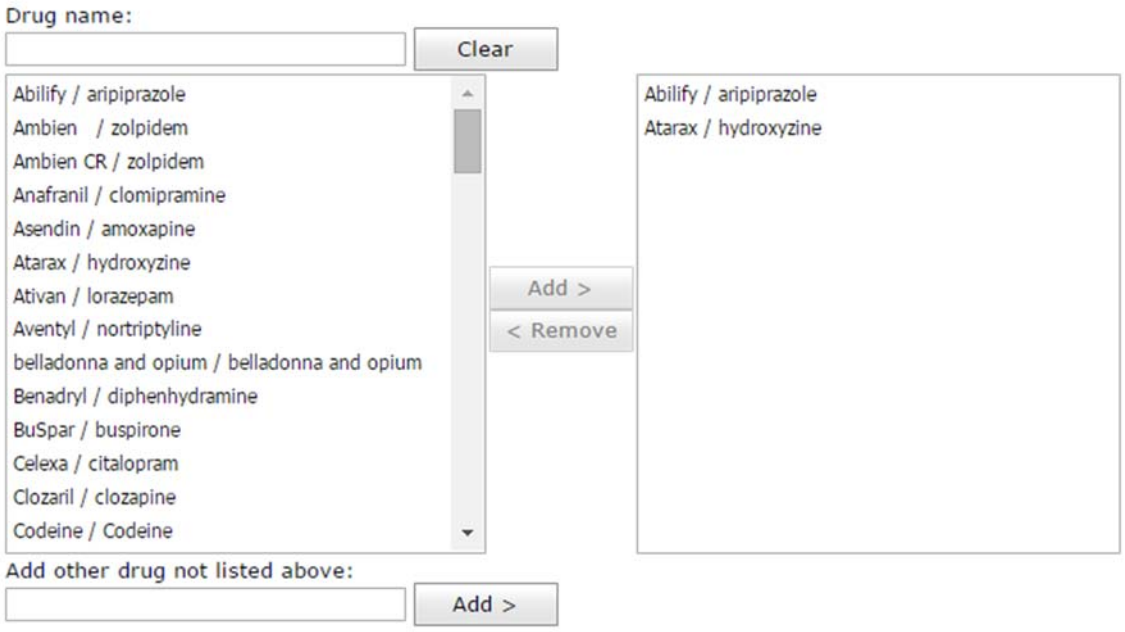
28. Have you or someone else been injured as a result of your drinking? (AUDIT_9)
No (0)
Yes, but not in the last year (1)
Yes, during the last year (2)

29. Has a relative or friend or a doctor or another health worker been concerned about your drinking or suggested you cut down? (AUDIT_10)

No (0)
Yes, but not in the last year (2)
Yes, during the last year (4)

INSERT PAGE BREAK HERE

30. Please begin entering the name of any medication you are currently taking in the box on the left. You can enter the brand name or the generic name. When you see the medication you are looking for, highlight it and click the "Add >" button to move the medication name to the box on the right. (MedsList)



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You indicated that you take [FILL] medications. Please answer the following questions for [FIRST MEDICATION INDICATED].

30a. What does the label on the bottle or package say is the amount of medication contained in one dose of this medication? Make sure to include the decimal point if there is one.

DOSAGE _____ **(MedsDose_1)**

30b. Is this: **(MedsUnits_1)**

___ mg (0)

___ g (1)

___ other (2)

30c. How many doses do you or did you take of this medication each day? (If the number of doses you took each day changed over the past **6 months**, please tell us the most recent number of doses you took each day.)

DOSES _____ **(MedsNumDose_1)**

30d. In the past **3 months**, during how many months did you take this medication?

MONTHS _____ **(MedsMonths_1)**

30e. Are you taking this medication now? **(MedsNow_1)**

___ Yes **(1)**

___ No **(0)**

30f. If yes, on how many of the past **30 days** did you take this medication?

DAYS _____ **(Meds30d _1)**

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31. Below is a list of problems and complaints that veterans sometimes have in response to stressful life experiences. Please read each one carefully, and mark the box to indicate how much you have been bothered by that problem in the **last 2 weeks**.*

No.	Response	Not at all (1)	A little bit (2)	Moderately (3)	Quite a bit (4)	Extremely (5)
1.	Repeated, disturbing *memories, thoughts, or images* of a stressful experience from the past? (PCLC_1)					
2.	Repeated, disturbing *dreams* of a stressful experience from the past? (PCLC_2)					
3.	Suddenly *acting* or *feeling* as if a stressful experience *were happening* again (as if you were reliving it)? (PCLC_3)					
4.	Feeling *very upset* when *something reminded* you of a stressful experience from the past? (PCLC_4)					
5.	Having *physical reactions* (e.g., heart pounding, trouble breathing, or sweating) when *something reminded* you of a stressful experience from the past? (PCLC_5)					
6.	Avoid *thinking about* or *talking about* a stressful experience from the past or avoid *having feelings* related to it? (PCLC_6)					
7.	Avoid *activities* or *situations* because they *remind you* of a stressful experience from the past? (PCLC_7)					
8.	Trouble *remembering important parts* of a stressful experience from the past? (PCLC_8)					
9.	Loss of *interest in things that you used to enjoy?* (PCLC_9)					
10.	Feeling *distant* or *cut* off from other people? (PCLC_10)					

11.	Feeling *emotionally numb* or being unable to have loving feelings for those close to you? (PCLC_11)					
12.	Feeling as if your *future* will somehow be *cut short*? (PCLC_12)					
13.	Trouble *falling* or *staying asleep*? (PCLC_13)					
14.	Feeling *irritable* or having *angry outbursts*? (PCLC_14)					
15.	Having *difficulty concentrating*? (PCLC_15)					
16.	Being *"super alert"* or watchful on guard? (PCLC_16)					
17.	Feeling *jumpy* or easily startled? (PCLC_17)					

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The next set of questions asks about thoughts you may have had of hurting yourself or others in the **past 2 months**.

32. In the **past 2 months**, did you…*

	Yes (1)	**No (0)**
a. Want to harm yourself or to hurt or to injure yourself? (SI_a)	☐	☐
b. Think about suicide? (SI_b)	☐	☐
c. Have a suicide plan? (SI_c)	☐	☐
d. Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? (SI_d)	☐	☐
e. Deliberately injure yourself without intending to kill yourself? (SI_e)	☐	☐
f. Attempt suicide? (SI_f)	☐	☐
g. Did you ever make a suicide attempt? (SI_g)	☐	☐

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[IF PARTICIPANT SCORES POSITIVE ON ITEM 33 ABOVE, ADMINISTER Q33b_sub BELOW.]

32b_sub. Do you **currently**…*

	Yes (1)	**No (0)**
a. Want to harm yourself or to hurt or to injure yourself? (SI_sub_a)	☐	☐
b. Think about suicide? (SI_sub_b)	☐	☐
c. Have a suicide plan? (SI_sub_c)	☐	☐
d. Plan any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? (SI_sub_d)	☐	☐

Appendix H:

Quad Chart

Effectiveness and Acceptability of Stellate Ganglion Block (SGB) for Treatment of PTSD Symptoms
Log # 13046044 - FY 13 Applied Research and Advanced Technology Development Psychological Health Award
W81XWH-15-2-0015

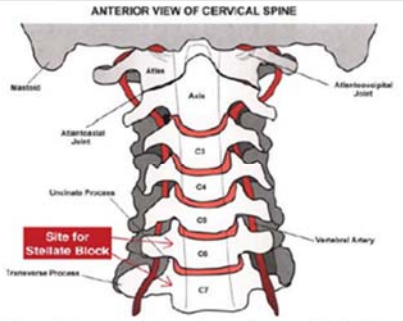
PI: Bradford Walters, MD, PhD **Org: RTI International** **Award Amount: $2,198,738.00**

Study Aims

- Determine effectiveness of SGB vs placebo in treating PTSD symptoms
- Describe the degree to which study participants are accepting of SGB

Approach

- Conduct a double-blind, sham-procedure-controlled, randomized clinical trial of 240 active duty participants with PTSD at 3 sites; primary outcome measure is CAPS-5 pre- and 8-weeks-post intervention
- Conduct focus groups and structured interviews with RCT participants (as well as spouses and clinical providers) to characterize the acceptability of the procedure



Accomplishment: IRB protocol submitted to and approved by the Womack Army Medical Center IRB. Protocol materials submitted to HRPO for review. Preparations at sites underway – including hiring and training of on-site Research Coordinators.

Timeline and Cost

Activities CY	15	16	17	18
Conduct Randomized Controlled Trial				
Conduct Qualitative Study				
Analyze Data				
Prepare and Submit Reports, Manuscripts and Briefings				
Estimated Budget ($K)	**$561**	**$855**	**$677**	**$106**

Updated: 2/28/2016

CY 15 (funded 3/2015)
Prepare Regulatory Documents & Research Protocols
- ☑ Approved by WAMC IRB
- ☑ Submitted to HRPO

Develop Study Infrastructure
- ☑ Instrumentation programming complete
- ☑ RC identified for each site and training materials in development

CY 16
Prepare Regulatory Documents & Research Protocols
- ☐ Approved by HRPO

Develop Study Infrastructure
- ☑ In place & operational

Collect, Analyze, and Disseminate Data
- ☐ Subjects enrolling, collecting data

CY 17
Collect, Analyze, and Disseminate Data
- ☐ Enrollment complete
- ☐ Analyses Complete and data dissemination underway

Comments/Challenges/Issues/Concerns
- Timely HRPO approval needed in order to remain on schedule

Budget Expenditure to Date: Projected: $560,755 Actual: $600,202